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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,380	12/20/2000	Hassan Jomaa	12964.18	2374

7590

07/21/2006

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EXAMINER

CLARDY, S

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,380

Applicant(s)

JOMAA, HASSAN

Examiner

S. Mark Clardy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003, and decision to revive.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-8,17,21,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8,17,21,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/07/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-3, 6-8, 17, 21, and new claims 24 and 25 are pending in this application which has been filed under 35 USC 371 as a national stage application of PCT/EP99/04260, filed June 23, 1999. This application has been revived after having abandoned for failure to respond to the office action mailed September 9, 2002.

The application as originally filed lacked unity of invention under 37 CFR 1.475 (MPEP 1850, 1893.03(d)), and was subject to restriction. The previously withdrawn claims have been canceled. All claims are now drawn to the elected invention, comprising:

Group I, claim(s) 1-2, drawn to compositions comprising:

- A. an anti-infectious active agent that inhibits the 2C-methylerythrose-4-metabolic pathway
- B. a lipid metabolism inhibitor

Group VI (and IX), wherein A is a phosphorus (and oxazole) containing compound

Group II, wherein B is a squalene synthase inhibitor

Group XII, drawn to methods of using lipid metabolism inhibitors as herbicides.

The elected species comprises the following active agents:

- A. Alendronate¹: $\text{HO} - \text{C}(\text{PO}_3\text{H}_2)_2 - (\text{CH}_2)_3 - \text{NH}_2$
- B. Fosmidomycin²:

$$\begin{array}{c} \text{O} \\ \parallel \\ \text{O} = \text{CH} - \text{N} - (\text{CH}_2)_3 - \text{P} - \text{OH} \\ | \qquad \qquad | \\ \text{OH} \qquad \qquad \text{OH} \end{array}$$

¹ Alendronic acid: 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid

² 3-(N-formyl-N-hydroxyamino)propylphosphonic acid

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The rejection of claims 3, 4, 6, and 21 under 35 U.S.C. 101 and 112, second paragraph, is withdrawn in response to applicants' amendment.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-8, 17, 21, 24, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-10, 21 and 22 of U.S. Patent No. 10/363,280. Although the conflicting claims are not identical, they are not patentably distinct from each other because they use derivatives of the same bisphosphonic acid (A) component in combination with fosmidomycin.

Claims 7, 8, and 17 are now objected to because of the following informalities: these claims are multiply dependent on claims which have been canceled. Appropriate correction is required.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-8, 17, 21, 24, and 25 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of U Sheffield (PCT WO 97/43437), Teijin Ltd (JP 61-106504, and JPO Abstract), and Kamuro et al (US 4,846,872).

U Sheffield teaches that prenyl transferase and isopentenylpyrophosphate isomerase inhibitors are useful therapeutic agents for bone disease and cancer (abstract). Again, this reference further teaches that inhibitors of lipid metabolism, specifically prenyl transferase (farnesyl pyrophosphate synthase) and isopentenylpyrophosphate isomerase (IPI) inhibitors (p. 18, lines 15-25) such as alendronate (p. 29, lines 1-3; p. 43, "Methods") are useful as fungicides and herbicides (p. 17, lines 4-11; p. 26, line 26 through p. 27, line 3; claim 14). Thus applicants' elected "A" component was a known herbicidal agent, and application of these materials to animals as well as plants was known in the art.

Teijin Ltd, again, teaches that fosmidomycin was also a known herbicidal agent (Abstract and structures on p. 39).

Kamuro et al, again, teach that it was also known to combine fosmidomycin with additional herbicidal agents (col 2, lines 50-53), specifically ametryn and diuron (abstract; column 1, lines 5-41).

One of ordinary skill in the art would be motivated to combine these references because they disclose the herbicidal utility of the elected compounds. It is *prima facie* obvious to

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combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 205 USPQ 1069.

Thus it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the two known compounds alendronate and fosmidomycin because they are known herbicidal agents. Absent evidence of unexpected results, the combination is obvious. No data has been provided in the specification to demonstrate any unexpected herbicidal characteristics of the elected composition.

Applicant argues that the compositions are patentable because the rejection is based upon their herbicidal utility, while the utility disclosed herein (as well as the bulk of U Sheffield) pertains to pharmaceutical utility. However, for composition claims, the end utility is irrelevant. The prior art suggests that the combination is a useful herbicide. Even if another unrelated utility were to be discovered, the combination itself would remain obvious.

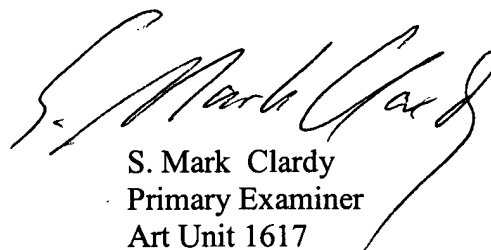
No unobvious or unexpected results are noted; no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Mark Clardy whose telephone number is 571-272-0611. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S. Mark Clardy
Primary Examiner
Art Unit 1617

July 18, 2006